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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,944	08/08/2001	Douglas C. Harnish	0630/1G704US2	2000
32801	7590	12/18/2003	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 5257 NEW YORK, NY 10150-5257			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 12/18/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,944

Applicant(s)

HARNISH ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The amendment and response filed on 9/16/2003 is acknowledged. Applicant's request for rejoining the process is acknowledged. When the claims drawn to the product is allowable, the process claims including all the limitations of allowable subject matter would be rejoined.

Claims 1-25 are pending and claims 12-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) for reason of record.

Claims 1-11, and 25 are under consideration.

Claim Rejections - 35 USC § 112

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicant's argument is persuasive.

Claim Rejections - 35 USC § 103

Claims 1-11, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harnish et al (1998, J. Biol. Chem. vol. 273, pages 9270-8) and Ameis et al (1990, J. Biol. Chem. vol. 265, pages 6552-5) in view of Norris et al (1995, J. Biol. Chem. vol. 270, pages 22777-82), US Pat 5,908,859 (June 1, 1999, or Dichek et al (1998, J. Biol. Chem. vol. 273, pages 1896-903), and further in view of Kwok et al (1994, Nature, vol. 270, pages 177-8, abstract only).

Claims 1-10 and 25 are interpreted as drawn to recombinant cell (more specifically a hepatocarcinoma cell in claim 9, HepG2 cell in claim 10) containing 3 DNA constructs, i.e. 1) DNA construct expressing a estrogen receptor (more specifically human one in claim 2, human estrogen receptor alpha (ER-alpha) in claim 3); 2) DNA construct expressing a transcription coactivator C/EBP; 3) a reporter construct linking various art-known reporters listed in claim 7 (more specifically luciferase in claim 8) to hepatic lipase promoter/enhancer (more specifically -1557 to +43 of human HL gene in claim 6). Claim 11 is interpreted as drawn to the recombinant cell of claim 1 for screening useful compounds affecting the ERalpha and/or C/EBP dependent transcription activation of hepatic lipase promoter/enhancer in multi-well format capable of detecting the reporter being used.

Applicant argues that p300 and CBP expressing vector of the cited art and "C/EBP transcription factor" expressing vector recited in instant base claims are different and the Office's obviousness analysis does not give any connection between HL promoter and ER, thus the art as a whole would not give one in ordinary skill motivation to arrive at the instantly claimed invention with a reasonable expectation of success. Applicant's arguments have been fully considered but found unpersuasive for the following reasons.

The instant claims are drawn to **a recombinant cell per se** with vectors encoding two proteins and a known- promoter linked to known reporter.

The Office cites Kwok et al to show that CBP works with CREB in order to activate the same enhancer element. CREB is not discovered by applicant but known

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in the art before the effective filing date of instant application. CBP vector of Harnish et al could have been substituted by the art-known CREB in order to activate the same enhancer element with a reasonable expectation of success since CREB encoding sequence is known in the art. As stated in the previous Office action, the primary references teach every limitations of the claimed recombinant cell except CREB. However, Kwok et al teach that CBP could act as a functional equivalent of CREB in terms of CBP/CREB related transcriptional studies.

Further, Ameis et al teach the promoter/enhancer of interest i.e. hepatic lipase promoter/enhance and Harnish et al along with Dichek et al suggest that regulating the hepatic lipase gene with estrogen receptor along with CBP and CREB might be a good target in preventing heart diseases and other lipid-metabolism-related diseases in menopausal women. Note the entire Dichek et al and columns 1-2 of the '859 patent, Materials and Methods at page 22777-8, and the last paragraph of Norris et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make and use the claimed invention with reasonable expectation of success.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
December 15, 2003


MISOOK YU, EXAMINER
ART UNIT 1642
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